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Date of Deposit: 12/13/2001

Case No. 8465/17

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )  
Nielsen et al. )  
Serial No. To Be Assigned ) Examiner: To Be Assigned  
Filing Date: Herewith ) Group Art Unit No.: To Be Assigned  
For MEDICAL PUNCTURING DEVICE )  
 )  
 )

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This is a continuing patent application of application number 09/115,340 filed July 14, 1998. Prior to examination on the merits, please enter the amendment below.

**In the Specification:**

Please amend the specification as follows:

Please insert the following paragraph immediately before the first line:

--This application is a continuation of application number 09/115,340, filed July 14, 1998, pending, which is hereby incorporated by reference herein.--

**In the Claims:**

Please amend the claims as follows:

Please cancel claims 1-10.

Please add the following new claims:

11. An infusion device comprising:

    a housing;

    a cavity within the housing;

a soft cannula extending from the housing and being in flow communication with the cavity, said soft cannula having an outer tip;

a medication bore within the housing for leading medication to said cavity;

a puncturing device adapted to be connected to said housing, said puncturing device comprising a rigid needle being adapted to extend through the cannula and beyond the outer tip thereof when the puncturing device is connected to said housing, said rigid needle being at one end adapted for facilitating puncturing and including at the opposite end a hub;

said hub having a hinge, a handle part and a single shield part with a first end and a second free end, said first end of the shield part being pivotably connected to the handle part by means of said hinge, whereby said second free end is pivotable with respect to said hinge;

said shield part being adapted to cover the rigid needle when pivoted with respect to said hinge, the second free end of the shield part extending beyond said one end of the rigid needle; and

said hub further having a locking mechanism on the shield part and the handle part, the locking mechanism being adapted to interlock the shield and the handle part in a pivoted position of the shield part when the puncturing device is disconnected from the housing and the shield part is pivoted to cover the rigid needle.

12. An infusion device as claimed in claim 11, wherein the shield part comprises a recess for accommodating the rigid needle.

13. An infusion device as claimed in claim 11, wherein the shield part has an essentially U-shaped cross section.

14. An infusion device as claimed in claim 11, wherein the locking mechanism on the handle part comprises two arms having on their opposed sides barbs adapted to interlock with the corresponding locking mechanism of the shield part.

15. An infusion device as claimed in claim 14, wherein the edges of the barbs are tapered so as to facilitate the insertion into the corresponding locking mechanism of the shield part.

16. An infusion device as claimed in claim 15, wherein the hub is formed as a single part and where the hinge between the handle part and the shield part is an area with a reduced rigidity.

17. An infusion device as claimed in claim 15, wherein the hub is made of a plastics material.

18. An infusion device as claimed in claim 15, wherein gripping means are provided on the shield part and the handle part, said gripping means being adapted to lock the hub to the housing.

19. An infusion device as claimed in claim 11, wherein the locking mechanism on the shield part comprises two side flanges adapted to interlock with the corresponding locking mechanism of the handle part.

20. An infusion device as claimed in claim 19, wherein the edges of the flanges are tapered so as to facilitate the insertion into the corresponding locking mechanism of the handle part.

21. An infusion device as claimed in claim 11, wherein the shield part comprises an operating handle, the operating handle thereby being pivotable with respect to the handle part of the hub.

22. An infusion device as claimed in claim 11, wherein the hub is formed as a single part and where the hinge between the handle part and the shield part is an area with a reduced rigidity.

23. An infusion device as claimed in claim 11, wherein the hub is made of a plastics material.

24. An infusion device as claimed in claim 11, wherein gripping means are provided on the shield part and the handle part, said gripping means being adapted to lock the hub to the housing.

25. An infusion device as claimed in claim 11, wherein gripping means are provided on the shield part and the handle part, said gripping means being adapted to lock the hub to the housing, wherein the shield part comprises an operating handle, the operating handle being pivotable with respect to the handle part of the hub, and wherein pressing the

handle part against the operating handle will release the gripping means and thereby the puncturing device from the housing.

26. An infusion device comprising:

a housing;

a cavity within the housing;

a soft cannula extending from the housing and being in flow communication with the cavity, said soft cannula having an outer tip;

a medication bore within the housing for leading medication to said cavity;

a puncturing device adapted to be connected to said housing, said puncturing device comprising a rigid needle being adapted to extend through the cannula and beyond the outer tip thereof when the puncturing device is connected to said housing, said rigid needle being at one end adapted for facilitating puncturing and including at the opposite end a hub;

said hub having a hinge, a handle part and a single shield part with a first end and a second free end, said first end of the shield part being pivotably connected to the handle part by means of said hinge, whereby said second free end is pivotable with respect to said hinge;

said shield part being adapted to cover and bend the rigid needle when the shield part is pivoted with respect to said hinge, the second free end of the shield part extending beyond said one end of the rigid needle; and

said hub further having a locking mechanism on the shield part and the handle part, the locking mechanism being adapted to interlock the shield and the handle part in a pivoted position of the shield part when the puncturing device is disconnected from the housing and the shield part is pivoted to cover the rigid needle.

27. An infusion device as claimed in claim 26, wherein the shield part comprises a recess for accommodating the rigid needle.

28. An infusion device as claimed in claim 26, wherein the shield part has an essentially U-shaped cross section.

29. An infusion device as claimed in claim 26, wherein the locking mechanism on the handle part comprises two arms having on their opposed sides barbs adapted to interlock with the corresponding locking mechanism of the shield part.

30. An infusion device as claimed in claim 29, wherein the edges of the barbs are tapered so as to facilitate the insertion into the corresponding locking mechanism of the shield part.

31. An infusion device as claimed in claim 26, wherein the locking mechanism on the shield part comprises two side flanges adapted to interlock with the corresponding locking mechanism of the handle part.

32. An infusion device as claimed in claim 31, wherein the edges of the flanges are tapered so as to facilitate the insertion into the corresponding locking mechanism of the handle part.

33. An infusion device comprising:

a housing;

a cavity within the housing;

a soft cannula extending from the housing and being in flow communication with the cavity, said soft cannula having an outer tip;

a bore for leading medication to said cavity;

a puncturing device adapted to be connected to said housing, said puncturing device comprising a needle being adapted to extend through the cannula and beyond the outer tip thereof when the puncturing device is connected to said housing, said needle being at one end adapted for facilitating puncturing and comprising at opposite end of a hub;

said hub comprising a handle part and a shield part, said shield part being pivotable in relation to the handle part;

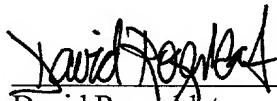
said hub further comprising a locking mechanism on the shield part and the handle part, the locking mechanism being adapted to interlock the shield and the handle part in a pivoted position of the shield part when the puncturing device is disconnected from the housing, whereby the rigid needle is covered by the shield; and

wherein the needle is bendable when the shield part and the handle part are locked together, whereby the bendable needle provides a biasing effect between the locking mechanism on the shield part and the handle part, and whereby the bendable needle closely abuts on the shield to ensure that unintended contact with the needle is avoided.

**REMARKS**

With this Amendment, the application is in condition for early action on the merits. Should the Examiner deem a telephone conference to be helpful in expediting allowance of this application, the Examiner is invited to call the undersigned at the telephone number shown below.

Respectfully submitted,

  
\_\_\_\_\_  
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**SUBMISSION OF FORMAL DRAWINGS**

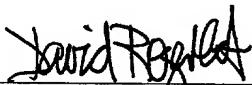
Assistant Commissioner for Patents  
Washington, D.C. 20231

Attn: Official Draftsman

Dear Sir:

We enclose 6 sheets of formal drawings.

Respectfully submitted,

  
\_\_\_\_\_  
David Rozenblatt

David Rozenblatt, Reg. No. 47,044  
Attorney for Applicants

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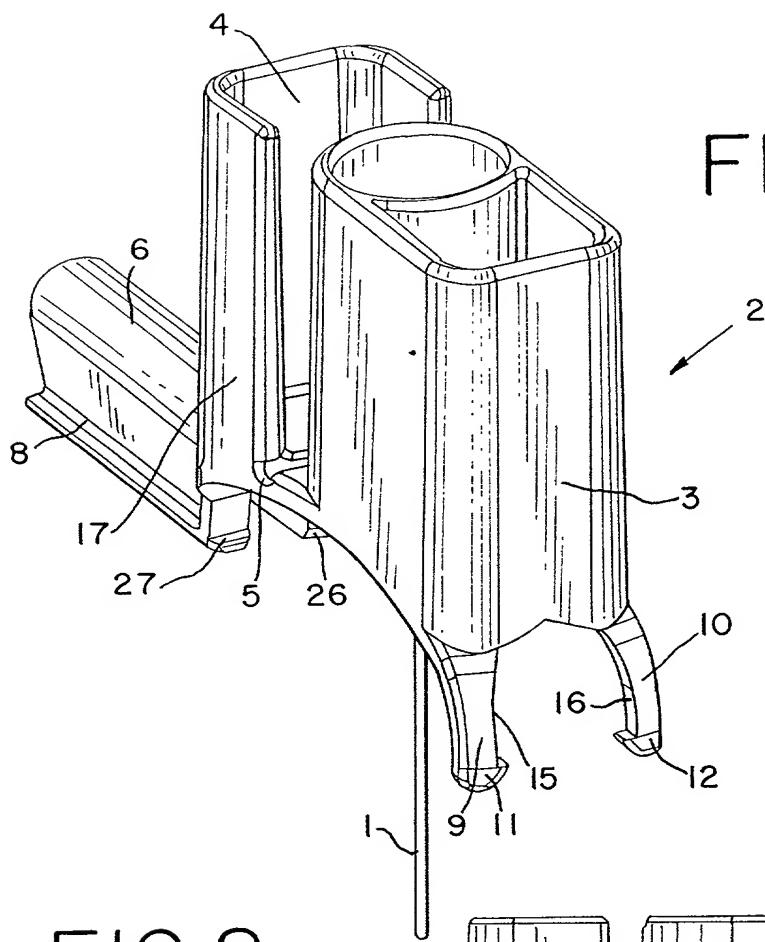


FIG. 1

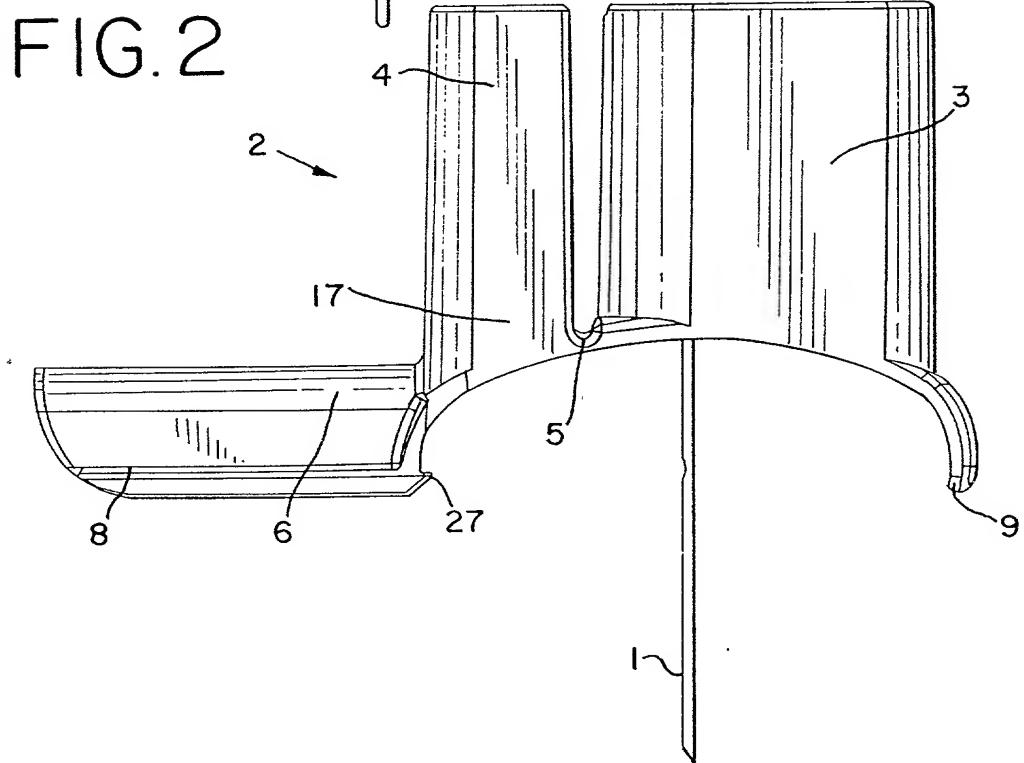


FIG. 2

FIG. 3

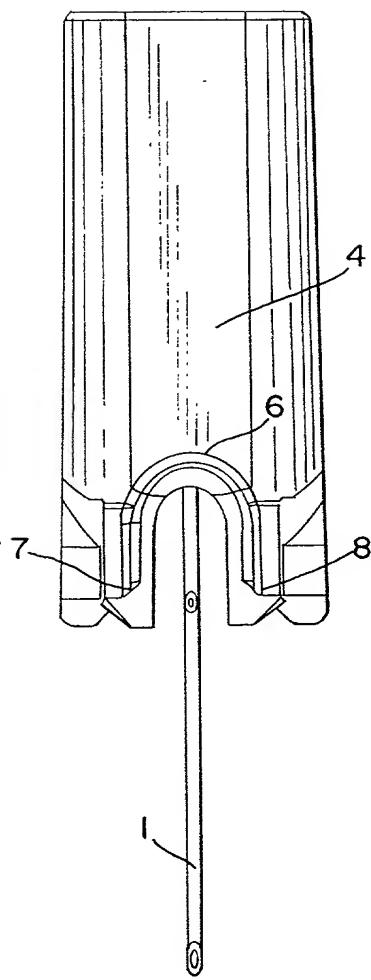


FIG. 4

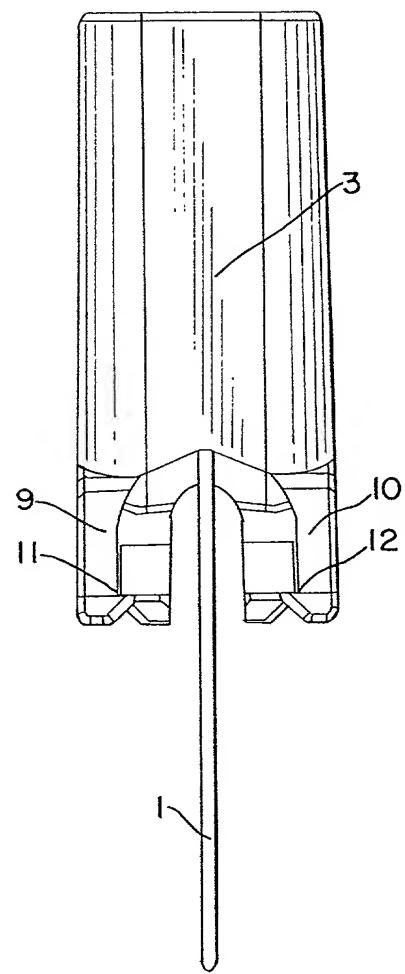


FIG. 5

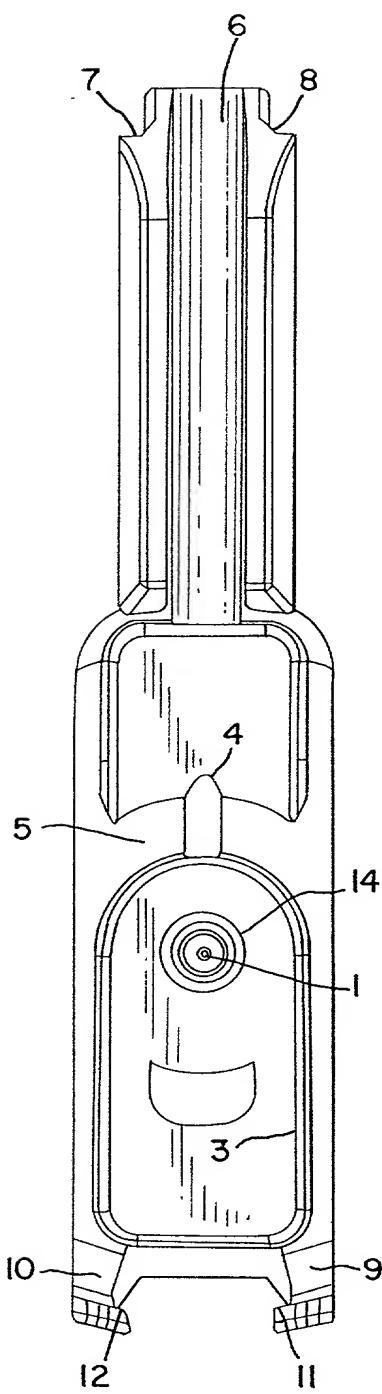


FIG. 6

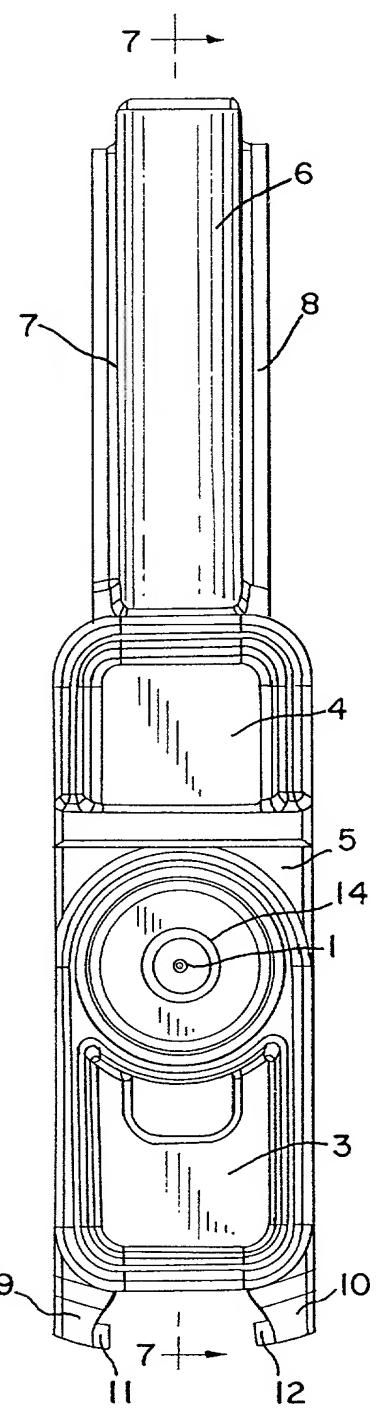


FIG. 7

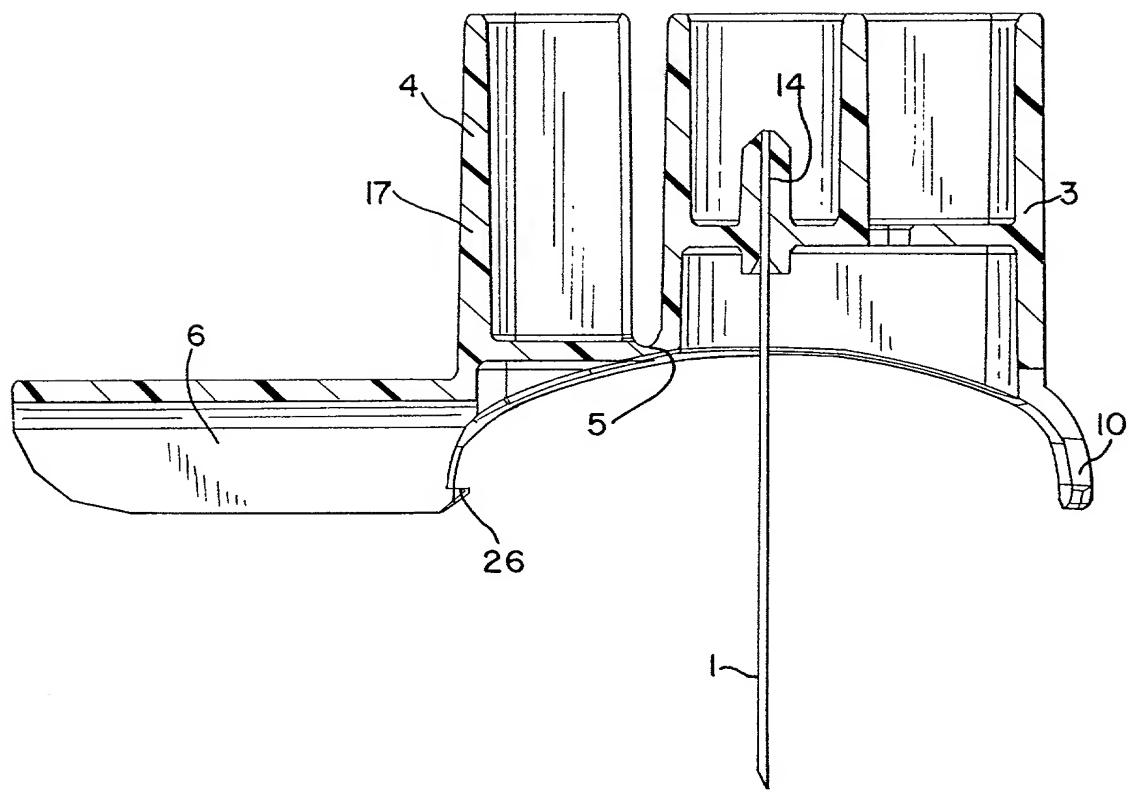


FIG. 8

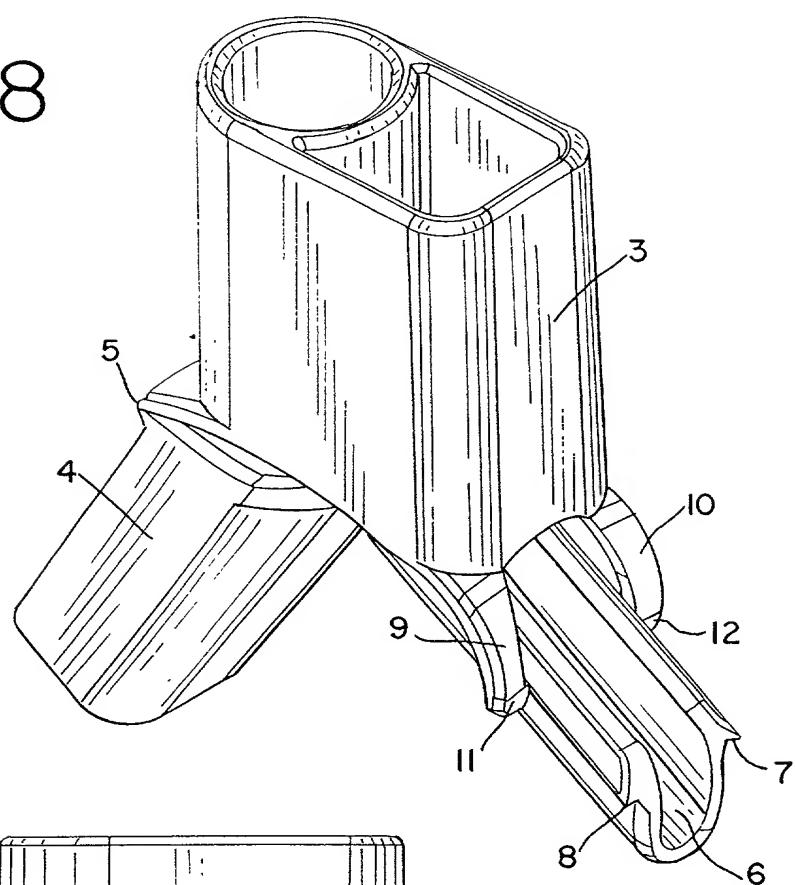


FIG. 9

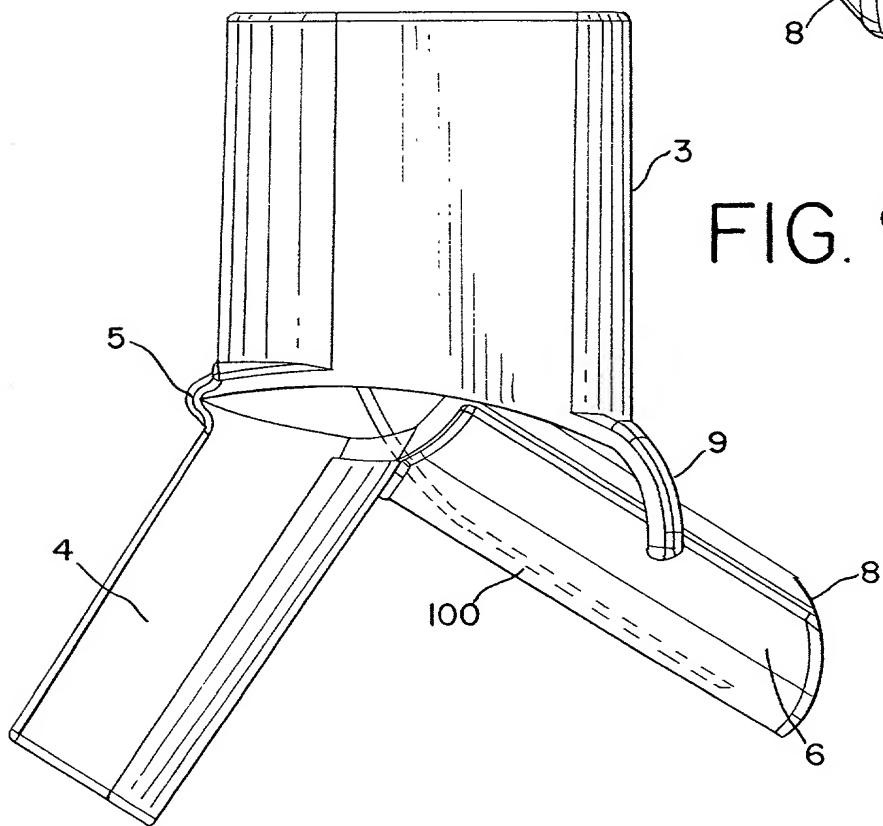


FIG. 10

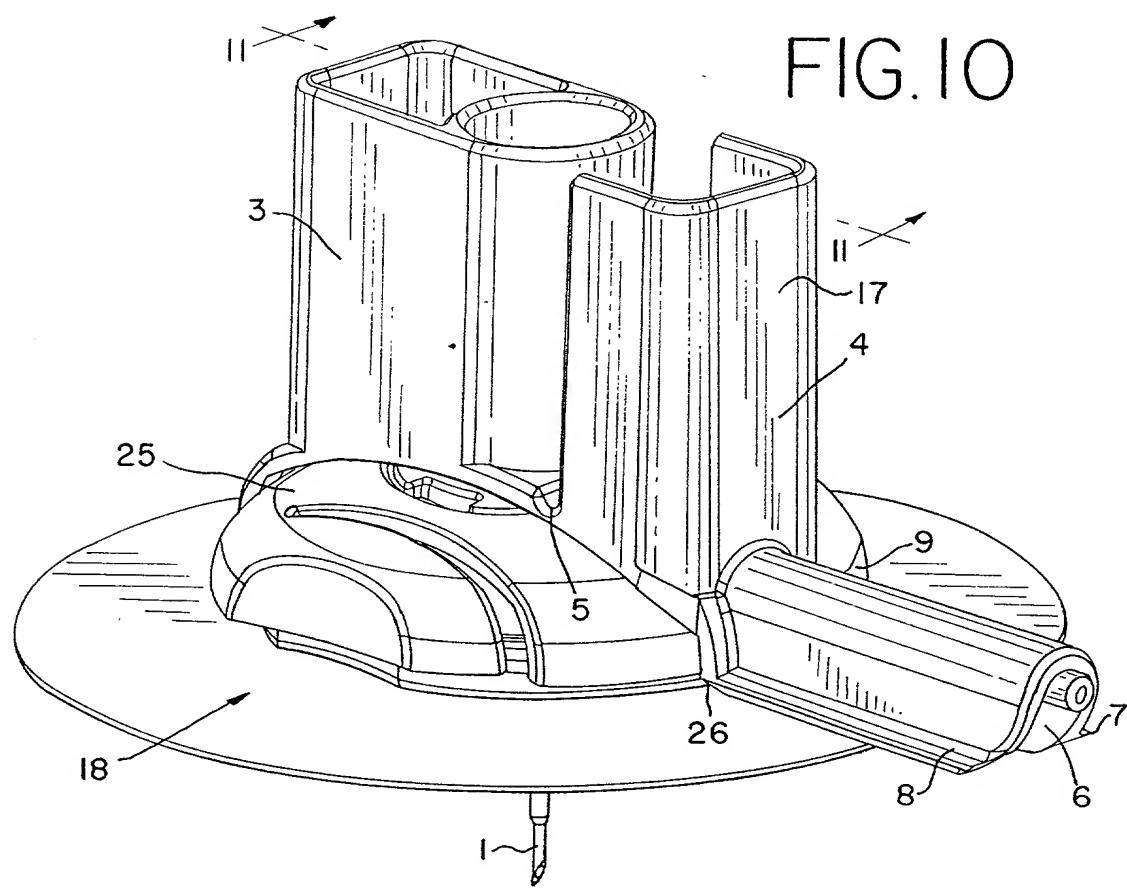


FIG. II

